

K974719 PHACOPAKJan 20, 1998
33 days to decisionK974719 · Product code: **HQC** · Ophthalmic
Source: <https://www.510kdatabase.net/k974719/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Phacofragmentation (HQC)
Date received	Dec 18, 1997
Decision date	Jan 20, 1998
Days to decision	33 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Paradigm Medical Industries, Inc.
Location	Salt Lake City, UT, US
Contact	RICHARD DIRKSON
510(k) history	10 submissions · 10 cleared · 1995-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k974719/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 18, 2026